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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR       | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|-----------------|-------------|----------------------------|------------------------|------------------|
| 10/629,649      | 07/30/2003  | Nigel Robert Arnold Beeley | 18528.636 / 0212-CIP-9 | 6846             |

28381 7590 09/14/2005

ARNOLD & PORTER LLP  
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555 TWELFTH STREET, N.W.  
WASHINGTON, DC 20004-1206

EXAMINER

RUSSEL, JEFFREY E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/629,649

Applicant(s)

BEELEY ET AL.

Examiner

Jeffrey E. Russel

Art Unit

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**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 01 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: None.  
Claim(s) objected to: 74,80,86,92,98,104 and 110.  
Claim(s) rejected: 1-6,12-16,22-26,32-36,42-46,52-56,62-66,72,73,75-79,81-85,87-91,93-97,99-103,105-109 and 111-113.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

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1. The proposed amendment after final rejection filed September 1, 2005 raises the following new issue under 35 U.S.C. 112, second paragraph: Each of independent claims 1, 12, 22, 32, 42, 52, and 62 would include the phrase "said at least one symptom of PCOS". However, the proposed amendment would eliminate any antecedent basis for these phrases. Note that claim 1 would need to be amended so that there is still antecedent basis for the limitation in claim 2.

2. The proposed amendment after final rejection filed September 1, 2005 would have overcome the rejections set forth in sections 3 and 4 of the final Office action mailed June 7, 2005.

The examiner agrees that when the instant claims are otherwise allowable, the provisional obviousness-type double patenting rejection set forth in section 5 of the Office action can be withdrawn consistent with the procedures set forth in MPEP 822.01.

Applicants' statement in the response filed September 1, 2005 satisfies the requirement set forth in section 6 of the final Office action.

3. The examiner maintains his position as to the effective filing date of Applicants' claims as set forth in section 7 of the final Office action. The examiner has not made a blanket statement of lack of written description for the claimed invention; rather, the examiner's analysis with citations to Applicants' specification is set forth at page 6, first full paragraph, of the action. The section of the specification of parent application 10/317,126 cited by Applicants as support for the claim terminology, as noted in the analysis, lists three specific exendins. This does not provide written descriptive support for all possible exendin peptides and analogs. See MPEP 2163.05. The references cited by Applicants at page 14, lines 2-3, of the response were not

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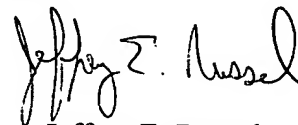
incorporated by reference into Applicants' specification. Considering WO Patent Application 99/07404 as representative of the references cited by Applicants, claim 1 of the reference embraces more than 256,000,000 different amino acid sequences. The compounds claimed by the WO Patent Application '404 are not described as being GLP-1 receptor agonists, nor are they described as being useful in the treatment of subjects suffering from PCOS. They are not evidence that the current claimed subject matter, i.e. the use of exendin peptides and analogs to treat subjects suffering from PCOS, was "common and well known" in the art at the time of the filing of the parent application, and the parent application's disclosure of three specific exendins does not evidence that Applicants contemplated the use of the vast number of exendin peptides and analogs known per se in the prior art. With respect to Howarth, cited by Applicants, this case concerns the application of the enablement provision of 35 U.S.C. 112, first paragraph, and its holdings and analyses do not apply to the written description requirement.

4. Because the examiner maintains his position with respect to the effective filing date of Applicants' claims, the examiner maintains the prior art rejections set forth in sections 9 and 10 of the final Office action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

September 9, 2005